

1 FLEXIBLE ENDOSCOPIC SURGICAL INSTRUMENT FOR INVAGINATION AND  
2 FUNDOPLICATION

3  
4 BACKGROUND OF THE INVENTION

5  
6 1. Field of the Invention

7 The invention relates to an endoscopic surgical instrument.  
8 More particularly, the invention relates to a flexible instrument  
9 for the transoral invagination and fundoplication of the stomach  
10 to the esophagus.

11  
12 2. State of the Art

13 Gastroesophageal fundoplication is a procedure for the  
14 treatment of gastroesophageal reflux disease (GERD), a condition  
15 in which gastric acids are regurgitated into the esophagus  
16 resulting in esophagitis, intractable vomiting, asthma, and  
17 aspiration pneumonia. The fundoplication procedure involves  
18 wrapping the fundus of the stomach around the lower end of the  
19 esophagus and fastening it in place. Traditionally, this  
20 procedure is accomplished via open surgery with the use of sutures  
21 to secure the plicated fundus of the stomach around the esophagus  
22 without penetrating (incising) the stomach.

1       U.S. Patent Number 5,403,326 to Harrison et al. discloses a  
2 method of performing endoscopic fundoplication using surgical  
3 staples or two-part surgical fasteners. The procedure disclosed  
4 by Harrison et al. involves performing two percutaneous endoscopic  
5 gastrotomies (incisions through the skin into the stomach) and the  
6 installation of two ports through which a stapler, an endoscope,  
7 and an esophageal manipulator (invagination device) are inserted.  
8 Under view of the endoscope, the esophageal manipulator is used to  
9 pull the interior of the esophagus into the stomach. When the  
10 esophagus is in position, with the fundus of the stomach plicated,  
11 the stapler is moved into position around the lower end of the  
12 esophagus and the plicated fundus is stapled to the esophagus.  
13 The process is repeated at different axial and rotary positions  
14 until the desired fundoplication is achieved. While, the  
15 procedure disclosed by Harrison et al. is a vast improvement over  
16 open surgery, it is still relatively invasive requiring two  
17 incisions through the stomach. Moreover, the procedure requires  
18 the manipulation of two different tools in order to position the  
19 fundus and to secure the fundus to the esophagus.

20

21       U.S. Patent Number 5,571,116 to Bolanos et al. discloses a  
22 non-invasive treatment of gastroesophageal reflux disease which  
23 utilizes a remotely operable invagination device and a remotely  
24 operable surgical stapler, both of which are inserted transorally

1 through the esophagus. According to the methods disclosed by  
2 Bolanos et al., the invagination device is inserted first and is  
3 used to clamp the gastroesophageal junction. The device is then  
4 moved distally, pulling the clamped gastroesophageal junction into  
5 the stomach, thereby invaginating the junction and involuting the  
6 surrounding fundic wall. The stapler is then inserted transorally  
7 and delivered to the invaginated junction where it is used to  
8 staple the fundic wall.

9  
10 Bolanos et al. disclose several different invagination  
11 devices and several different staplers. Generally, each of the  
12 staplers disclosed by Bolanos et al. has an elongate body and a  
13 spring biased anvil which is rotatable approximately 15° away from  
14 the body in order to locate the invaginated gastroesophageal  
15 junction between the body and the anvil. The body contains a  
16 staple cartridge holding a plurality of staples, and a staple  
17 firing knife. Each of the invagination devices disclosed by  
18 Bolanos et al. has a jaw member which is rotatable at least 45°  
19 and in some cases more than 90° to an open position for grasping  
20 the gastroesophageal junction. One of the chief disadvantages of  
21 the methods and apparatus disclosed by Bolanos et al. is that the  
22 stapler and the invagination device must be both be present in the  
23 esophagus at the same time. With some of the embodiments  
24 disclosed, the presence of both instruments is significantly

1 challenged by the size of the esophagus. In all of the  
2 embodiments, the invagination device is always laterally spaced  
3 apart from the stapler. Thus, the stapler cannot staple the  
4 invaginated tissue, per se, but can only staple tissue which is  
5 laterally adjacent to the invaginated tissue. The relatively  
6 small rotational movement of the anvil of the stapler further  
7 complicates the accommodation of tissue adjacent to the  
8 invaginated tissue. In addition, surgical staples have some  
9 inherent disadvantages as compared to other fasteners. The  
10 relatively small surface area of surgical staples allows them to  
11 pass through tissue over time, thereby unfastening the tissue and  
12 allowing the staples to migrate to other parts of the body.  
13 Bolanos et al. appears to recognize this disadvantage and proposes  
14 the application of a bolster or pledger to the tissues prior to  
15 stapling. Bolanos et al. do not explain how this can be  
16 accomplished transorally using the apparatus disclosed. In  
17 addition, while Bolanos et al. make a broad reference to other  
18 types of fasteners, the substantial size constraints imposed on  
19 the apparatus which are delivered transorally would seem to  
20 prohibit any type of fastener other than the staples shown by  
21 Bolanos et al. The actuating mechanism of the device disclosed by  
22 Bolanos et al. is somewhat awkward. In particular, the stapler  
23 anvil is biased to the open position, and it is not clear whether  
24 or not the stapler anvil can be locked in a closed position

1 without continuously holding down a lever. In addition, it  
2 appears that the staple firing trigger can be inadvertently  
3 operated before the anvil is in the closed position. This would  
4 result in inadvertent ejection of staples into the stomach or the  
5 esophagus of the patient.

6

7

#### SUMMARY OF THE INVENTION

8

9 It is therefore an object of the invention to provide an  
10 endoscopic surgical instrument for invagination and fundoplication  
11 of the stomach to the esophagus.

12

13 It is also an object of the invention to provide an  
14 endoscopic surgical instrument for invagination and fundoplication  
15 of the stomach to the esophagus which is minimally invasive.

16

17 It is another object of the invention to provide an  
18 endoscopic surgical instrument for invagination and fundoplication  
19 of the stomach to the esophagus utilizing fasteners which do not  
20 require bolsters or pledgers.

21

22 It is a further object of the invention to provide an  
23 endoscopic surgical instrument for invagination and fundoplication

1 of the stomach to the esophagus which is delivered transorally to  
2 the surgical site.

3

4 It is an additional object of the invention to provide an  
5 endoscopic surgical instrument for invagination and fundoplication  
6 of the stomach to the esophagus which is capable of plicating  
7 tissue directly in line with invaginated tissue.

8

9 Yet another object of the invention is to provide an  
10 endoscopic surgical instrument for invagination and fundoplication  
11 of the stomach to the esophagus which is easy to use and which  
12 cannot be accidentally triggered.

13

14 In accord with these objects which will be discussed in  
15 detail below, the endoscopic surgical instrument of the present  
16 invention includes a torsionally rigid but flexible tube having a  
17 proximal end and a distal end, a grasping and fastening end  
18 effector coupled to the distal end of the tube, and a manual  
19 actuator coupled to the proximal end of the tube. The grasping  
20 and fastening end effector preferably includes a separate grasper  
21 and a separate fastener. The manual actuator is coupled to the  
22 grasper and fastener of the end effector by a plurality of  
23 flexible cables which extend through the flexible tube. The tube  
24 preferably contains a lumen for receiving a manipulable endoscope

1 and the end effector preferably includes a passage for the distal  
2 end of the endoscope. The end effector has a store for a  
3 plurality of male fastener parts, a store for a plurality of  
4 female fastener parts, a rotatable fastener head for aligning a  
5 male fastener part and a female fastener part with tissues  
6 therebetween, a rotatable firing member for pressing a male  
7 fastener part through the tissues and into a female fastener part,  
8 and a rotatable grasper located between the fastener head and the  
9 firing member.

10

11 According to presently preferred embodiments, the overall  
12 diameters of the flexible tube and the end effector (when the  
13 fastener head is rotated to the open position and the grasper is  
14 rotated to the closed position) do not exceed approximately 20mm  
15 (and preferably less than 16mm) so that the instrument may be  
16 delivered transorally to the fundus of the stomach. The end  
17 effector preferably includes a substantially cylindrical  
18 stationary part which houses the store of male fastener parts and  
19 the firing member. Male fastener parts are ejected by the firing  
20 member through a substantially radial port in the substantially  
21 cylindrical stationary part of the end effector. The rotatable  
22 fastener head is hingedly coupled to a distal portion of the  
23 stationary part of the end effector and is rotatable from a first  
24 (open) position wherein the fastener head is rotated distally away

1 from the stationary part to a second (closed) position wherein the  
2 fastener head is rotated proximally toward the stationary part.  
3 The store of female fastener parts is preferably contained within  
4 the fastener head and a female fastener shuttle on the fastener  
5 head moves a female fastener from the store into alignment with  
6 the substantially radial port when the fastener head is rotated to  
7 the closed position.

8  
9       The presently preferred store for male fastener parts  
10 includes a longitudinal track arranged proximally of the rotatable  
11 firing member in which male fastener parts are arranged one behind  
12 the other. Male fastener parts are moved distally along the track  
13 by a first biasing member. According to one embodiment, the  
14 firing member includes a flange which blocks distal movement of  
15 male fastener parts while a male fastener part is being ejected.  
16 According to a presently preferred embodiment, a spring leaf with  
17 a pair of bent teeth engages the distal end of the next male  
18 fastener part in the track keeping it from moving off the track.  
19 When the firing member moves down to grab another male fastener  
20 part, the leaf is deflected allowing the next male fastener part  
21 to enter the firing member. The presently preferred store for  
22 female fastener parts includes an orthogonal chamber in which  
23 female fastener parts are stacked on top of each other and a  
24 second biasing member for moving the female fastener parts onto



1 the female fastener shuttle. The presently preferred female  
2 fastener shuttle is a sliding tray which is located adjacent to  
3 the store of female fastener parts. The second biasing member  
4 pushes female fastener parts into the tray and the tray moves  
5 laterally away from the store of female fastener parts when the  
6 rotatable fastener head is moved from the open position to the  
7 closed position.

8  
9 The rotatable fastener head, the firing member, and the  
10 grasper are preferably each controlled by an individual cable; and  
11 the proximal actuator includes three levers, each coupled to a  
12 respective cable, for individually operating the rotatable  
13 fastener head, the firing member, and the grasper. According to a  
14 presently preferred embodiment, the manual actuator includes a  
15 lock-out feature which prevents the inadvertent firing of male  
16 fastener members until the fastener head is rotated into the  
17 proper position. The manual actuator also includes a releasable  
18 lock for locking the grasper in the closed position.

19  
20 According to one embodiment, the male fastener member is a  
21 circular disk with a central upstanding barbed projection and the  
22 female fastener member is a circular disk with a central hole  
23 engageable by the barbed projection of a male fastener member.  
24 According to another, presently preferred embodiment, the female

1 fastener is rectangular with a central hole engageable by the  
2 barbed projection of a male fastener member. The female member is  
3 preferably provided with a plurality of weak peripheral extensions  
4 which allow the member to be held in the shuttle tray, but  
5 forcibly removed therefrom after it is coupled to a male member.

6

7       The apparatus of the invention is advantageously utilized in  
8 a fundoplication procedure. The instrument is prepared by  
9 inserting a manipulable endoscope into the proximal end of the  
10 instrument and threading the endoscope through the lumen of the  
11 flexible tube out through the end of the end effector. With the  
12 grasper closed and the rotatable fastener head in the first (open)  
13 position, the end effector is inserted into the mouth of the  
14 patient and guided down through the esophagus into the stomach  
15 with the aid of the endoscope. When the end effector is distal of  
16 the fundus (or lower esophageal sphincter), the grasper is opened  
17 and the end effector is raised toward the fundus so that the  
18 fundus and the lower end of the esophagus are located between the  
19 stationary part of the end effector and the grasper. The grasper  
20 is then closed to clamp together the tissue around the juncture of  
21 the esophagus and the fundus. With the grasper closed, the  
22 rotatable fastener head is closed, raising it up toward the fundus  
23 and lifting the fundus up against the esophagus. With the  
24 instrument in this configuration, the firing member is actuated

1 and a male fastener member is ejected out of the radial port,  
2 through the esophagus and the fundus, and into a female fastener  
3 member which is held by the tray in the rotatable fastener head.  
4 The firing member is then returned to its initial position moving  
5 the flange or the leaf away from the male fastener store and  
6 allowing a second male fastener to be pushed onto the second  
7 rotatable member. The rotatable fastener head is moved to the  
8 open position, releasing the female fastener, and returning the  
9 tray to the store of female fasteners to receive a second female  
10 fastener. The grasper is opened and the instrument may then be  
11 repositioned and the above procedure repeated until the desired  
12 fundoplication is achieved.

13

14 Additional objects and advantages of the invention will  
15 become apparent to those skilled in the art upon reference to the  
16 detailed description taken in conjunction with the provided  
17 figures.

18

#### 19 BRIEF DESCRIPTION OF THE DRAWINGS

20

21 Figure 1 is an enlarged broken perspective view of a first  
22 embodiment of a flexible endoscopic surgical instrument according  
23 to the invention with the end effector in a fully open position;

24

1        Figure 2 is an enlarged broken perspective view of the distal  
2 end of the instrument of Figure 1 with the grasper of the end  
3 effector in a closed position;

4

5        Figure 3 is an enlarged broken perspective view of the distal  
6 end of the instrument of Figure 1 with the end effector in a fully  
7 closed position;

8

9        Figure 4 is an enlarged proximal end view of the end effector  
10 removed from the instrument of Figure 1;

11

12        Figure 5 is a broken enlarged transparent side elevation view  
13 of the end effector in the fully closed position;

14

15        Figure 6 is a broken enlarged transparent side elevation view  
16 of the end effector in the fully closed position with a male  
17 fastener part ejected into a female fastener part;

18

19        Figure 7 is an enlarged side elevation view of a male  
20 fastener part according to the invention;

21

22        Figure 8 is an enlarged top view of the fastener part of  
23 Figure 7;

24

1        Figure 9 is an enlarged side elevation view of a first  
2 embodiment of a female fastener part according to the invention;

3  
4        Figure 10 is an enlarged top view of the fastener part of  
5 Figure 9;

6  
7        Figure 11 is an enlarged schematic view of the distal end of  
8 the instrument of Figure 1 adjacent the gastroesophageal junction  
9 in a first operative position;

10  
11       Figure 12 is a view similar to Figure 11 of the instrument in  
12 a second operative position;

13  
14       Figure 13 is a view similar to Figure 11 of the instrument in  
15 a third operative position;

16  
17       Figure 14 is a view similar to Figure 11 of the instrument in  
18 a fourth operative position;

19  
20       Figure 15 is a view similar to Figure 11 of the instrument in  
21 a fifth operative position;

22  
23       Figure 16 is a side elevation view of one side of a presently  
24 preferred manual actuator in a first operative position (grasper

1 closed and fastener head open) with the near side of the casing  
2 removed;

3

4 Figure 17 is an isometric view of one side of the actuator of  
5 Figure 16 with the near side of the casing removed;

6

7 Figure 18 is a side elevational view of the other side of the  
8 actuator of Figure 16 with the near side of the casing removed;

9

10 Figure 19 is an isometric view of the other side of the  
11 actuator of Figure 16 with the near side of the casing removed;

12

13 Figure 20 is a view similar to Figure 16 with the actuator in  
14 a second operative position (grasper open and fastener head open);

15

16 Figure 21 is a view similar to Figure 16 with the actuator in  
17 the midpoint a third operative position (grasper closed and  
18 fastener head partially closed);

19

20 Figure 22 is a view similar to Figure 16 with the actuator in  
21 a fourth operative position (grasper closed and fastener head  
22 closed);

23

1        Figure 23 is a view similar to Figure 16 with the actuator in  
2 a fifth operative position (grasper closed, fastener head closed,  
3 and male fastener part fired);  
4

5        Figure 24 is a view similar to Figure 21 of the other side of  
6 the manual actuator;  
7

8        Figure 25 is a perspective view of a presently preferred  
9 embodiment of the end effector in a first operative position;  
10

11       Figure 26 is a perspective view of the presently preferred  
12 embodiment of the end effector in a second operative position;  
13

14       Figure 27 is a perspective view of the presently preferred  
15 embodiment of the end effector in a third operative position;  
16

17       Figure 28 is a perspective view of the distal end of the  
18 presently preferred embodiment of the end effector in the third  
19 operative position;  
20

21       Figure 29 is a perspective view of the proximal end of the  
22 presently preferred embodiment of the end effector in the third  
23 operative position;  
24

1        Figure 30 is a perspective view of the major components of  
2 the presently preferred embodiment of the end effector in the  
3 third operative position;  
4

5        Figure 31 is a perspective view of the major components of  
6 the presently preferred embodiment of the end effector in a fourth  
7 operative position;  
8

9        Figure 32 is a perspective view of the stationary component  
10 and the grasper of the presently preferred embodiment of the end  
11 effector;  
12

13       Figure 33 is a perspective view of the grasper component and  
14 the fastener firing component of the presently preferred  
15 embodiment of the end effector;  
16

17       Figure 34 is a view similar to Figure 33 of the other side of  
18 the grasper component and the fastener firing component;  
19

20       Figure 35 is a perspective view of the top side of a  
21 presently preferred embodiment of a female fastener part in the  
22 female fastener carrier;  
23



1        Figure 36 is a perspective view of the bottom of the  
2 presently preferred female fastener part;

3

4        Figure 37 is a perspective view of the presently preferred  
5 female fastener part coupled to the male fastener part;

6

7        Figure 38 is a broken, partially cut away perspective view of  
8 an alternate preferred embodiment showing the firing member  
9 receiving a male fastener part;

10

11       Figure 39 is a view similar to Figure 38 from a different  
12 perspective;

13

14       Figure 40 is a view similar Figure 39 showing the firing  
15 member raised and the leaf preventing a male fastener part from  
16 moving off the track;

17

18       Figure 41 is a broken perspective view of the embodiment of  
19 Figures 38-40 showing the end effector with the firing member with  
20 a male fastener part engaged therein;

21

22       Figure 42 is a perspective view of the firing member and male  
23 fastener part engaged therein by a leaf spring;

24

1        Figure 43 is a perspective view of the firing member with the  
2 leaf spring disengaged from the male fastener part to release the  
3 male fastener part;

4

5        Figure 44 is a perspective view showing the end effector with  
6 the firing member with a male fastener part with the leaf spring  
7 disengaged from the male fastener part to release the male  
8 fastener part;

9

10       Figure 45 is a broken, partially cut away perspective view of  
11 the embodiment of Figures 38-44 showing the store of female  
12 fastener parts with a female fastener part in position to receive  
13 a male fastener part;

14

15       Figure 46 is a broken perspective view of the embodiment of  
16 Figures 38-45 showing the female fastener part shuttle in position  
17 to retrieve a female fastener part from the store of female  
18 fastener parts;

19

20       Figure 47 is a broken, partially cut away perspective view of  
21 the embodiment of Figures 38-46 showing the female fastener part  
22 shuttle in an intermediate position; and

23

1        Figure 48 is a broken, partially cut away perspective view of  
2 the embodiment of Figures 38-47 showing the female fastener part  
3 and male fastener parts coupled with the ejector spring engaging  
4 the barb of the male fastener part.

5  
6                    DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS  
7

8        Referring now to Figures 1 through 4, a first embodiment of  
9 an endoscopic surgical instrument 10 includes a torsionally rigid  
10 but flexible tube 12, preferably made from polyethylene, and  
11 having a proximal end 14 and a distal end 16, a grasping and  
12 fastening end effector 18 coupled to the distal end 16 of the tube  
13 12, and a manual actuator 20 coupled to the proximal end 14 of the  
14 tube 12. The manual actuator 20 is coupled to the end effector 18  
15 by three flexible cables 22, 24, 26 which extend through the  
16 flexible tube 12. Each of the cables is preferably formed from an  
17 outer coil sheath 22a, 24a, 26a, and an inner pull wire 22b, 24b,  
18 26b. The actuator 20 includes three levers 22c, 24c, 26c which  
19 are coupled to respective pull wires 22b, 24b, 26b. The tube 12  
20 also contains a lumen 28 for receiving a manipulable endoscope 2  
21 and the end effector 18 includes a passage 30 for the distal end 4  
22 of the endoscope 2. Preferably, the overall diameters of the  
23 flexible tube 12 and the end effector 18 (when in the position  
24 shown in Figure 2) do not exceed approximately 20mm (and are

1 preferably no more than 16mm) so that the instrument may be  
2 delivered transorally through the esophagus to the fundus of the  
3 stomach.

4  
5 The end effector 18 has a substantially cylindrical  
6 stationary member 31, a rotatable fastener head 40, and a grasper  
7 42. The stationary member 31 has a relatively flexible proximal  
8 portion 32 and a relatively rigid distal portion 34. The distal  
9 portion is rigid so that a store of male fastener parts and firing  
10 member can be located therein. The length of the rigid portion  
11 depends on the number of male fastener parts desired to be stored.  
12 The distal portion 34 has a flattened part 36 which angles down  
13 toward the distal end 38 of the stationary member 31. As will be  
14 described in more detail below with reference to Figures 5 and 6,  
15 the rotatable fastener head 40 is coupled to the distal end of the  
16 flattened portion 36 and is rotatable toward and away from the  
17 flattened portion 36 as seen best in Figures 2 and 3. The  
18 rotatable grasper 42 is coupled to the distal end of the flattened  
19 portion 36 proximal of the rotatable fastener head 40 and is  
20 rotatable toward and away from the flattened portion 36 as seen  
21 best in Figures 1 and 2. The rotatable fastener head 40 is  
22 coupled to the cable 24 so that its movement is controlled by the  
23 lever 24c and the grasper 42 is coupled to the cable 26 so that  
24 its movement is controlled by the lever 26c.

1        Referring now to Figures 4-6, the stationary member 31 of the  
2 end effector 18 includes a store 44 for male fastener parts, e.g.  
3 46, and a substantially radial port 48 through which male fastener  
4 parts are ejected. As will be described in more detail below with  
5 reference to Figures 7 and 8, the male fasteners have a  
6 substantially T-shaped profile and the store 44 is a substantially  
7 T-shaped track which is dimensioned to hold approximately six male  
8 fastener parts. A biasing spring 50 urges the male fasteners  
9 distally along the track into position adjacent the port 48. A  
10 rotatable firing member 52 is located adjacent to the distal end  
11 of the track 44 and is coupled to the cable 22. Thus, operation  
12 of the lever 22c (Figure 1) rotates the rotatable firing member 52  
13 thereby ejecting a male fastener part through the port 48. A  
14 lower flange 54 on the member 52 prevents distal movement of the  
15 fastener parts in the track 44 until the member 52 is rotated back  
16 to its original position.

17  
18        Referring generally to Figures 1-6, the rotatable fastener  
19 head 40 includes a store 56 for female fastener parts, e.g. 57,  
20 and a sliding tray 58 for moving female fastener parts out of the  
21 store 56. The sliding tray 58 is moved automatically by a wire  
22 link 60 which causes the tray to move away from the store 56 when  
23 the rotatable fastener head 40 is rotated from the open position  
24 (Figures 1 and 2) to the closed position (Figures 3-6). As will

1 be described in more detail below with reference to Figures 9 and  
2 10, according to one embodiment, the female fastener parts are  
3 generally disk shaped and are held in a stack in the store 56. A  
4 spring 62 biases the fastener parts into the tray 58 when the  
5 rotatable fastener head 40 is in the open position. The tray 58  
6 is dimensioned such that a single fastener part is retrieved from  
7 the stack and moved in the tray to a position opposite to the port  
8 48 when the rotatable fastener head 40 is rotated from the open  
9 position to the closed position.

10  
11 Turning now to Figures 7-10, a presently preferred male  
12 fastener part 46 has a disk shaped base 46a, a central upstanding  
13 shaft 46b, and tapered barb 46c at the end of the shaft.  
14 According to a preferred embodiment, the base is approximately 0.3  
15 inches in diameter and approximately .040 inches thick, the  
16 upstanding member is approximately 0.140 inches tall, and the barb  
17 is approximately 0.10 inches long. A first embodiment of a female  
18 fastening member 57 is a substantially flat disk 57a, having a  
19 central hole 57b, and four radially outward extending peripheral  
20 tabs 57c-57f. Four radial strain relief slits 57g-57j are  
21 preferably provided adjacent to the hole 57b. The female fastener  
22 is approximately 0.3 inches in diameter and approximately .040  
23 inches thick. Both the male fastener and the female fastener  
24 parts are made from biocompatible polymers. The barb 46c, the

1 shaft 46b, and the hole 57b are dimensioned such that the barb may  
2 be forced through the hole to lock the fastener parts together,  
3 but that once locked together, the parts will not easily separate.  
4 The peripheral tabs 57c-57f are dimensioned such that they hold  
5 the female fastener part in the sliding tray prior to being locked  
6 together with the male fastener part, but that they allow the  
7 female fastener part to be pulled out of the tray after it is  
8 locked together with the male fastener part. For example, the  
9 tabs are thin enough to bend, flex, or shear off when the female  
10 fastener part is pulled out of the tray.

11

12 As mentioned above, the instrument of the invention is  
13 advantageously utilized in a fundoplication procedure. With  
14 reference now to Figures 1, 2 and 11-15, the instrument 10 is  
15 prepared by inserting a manipulable endoscope 2 into the proximal  
16 end of the instrument and threading the endoscope through the  
17 lumen of the flexible tube 12 out through the end of the end  
18 effector 18. With the grasper 42 closed and the rotatable  
19 fastener head 40 in the first (open) position (as shown in Figures  
20 2 and 11, the end effector 18 is inserted into the mouth of the  
21 patient and guided down through the esophagus 3 into the stomach 5  
22 with the aid of the endoscope 2. When the grasper 42 and the  
23 rotatable fastener head 40 are distal of the fundus 7, the grasper  
24 42 is opened as shown in Figure 12 and the end effector is raised

1 toward the fundus 7 so that the fundus and the lower end of the  
2 esophagus 3 are located between the stationary part 31 of the end  
3 effector and the grasper 42. The grasper 42 is closed to hold the  
4 gastroesophageal junction as shown in Figure 13. The rotatable  
5 fastener head 40 is then rotated to the closed position, raising  
6 it up toward the fundus 7 and lifting the fundus 7 up against the  
7 esophagus 3 as shown in Figure 14. With the instrument in this  
8 configuration, the rotatable firing member (52 in Figures 5 and 6)  
9 is actuated and a male fastener member 46 is ejected out of the  
10 radial port 48, through the esophagus 3 and the fundus 7, and into  
11 a female fastener member 57 as shown in Figure 15. The rotatable  
12 firing member is then returned to its original position, moving  
13 the flange 54 away from the male fastener store 44 and allowing a  
14 second male fastener to be pushed onto the second rotatable member  
15 52. The rotatable fastener head 40 is moved to the open position,  
16 releasing the female fastener, and returning the tray to the store  
17 of female fasteners to receive a second female fastener. The  
18 grasper 42 is opened and the instrument may then be repositioned  
19 and the above procedure repeated until the desired fundoplication  
20 is achieved.

21

22 Figures 16 through 24 show a presently preferred manual  
23 actuator 100, according to the invention, which is provided with a  
24 lock-out feature to prevent the inadvertent firing of a male



1 fastener member before the rotatable fastener head is in the  
2 proper position and with a lockable lever for holding the grasper  
3 in the closed position. Referring now to Figures 16-20, and as  
4 seen best in Figures 17 and 19, the actuator 100 has a generally  
5 pistol-shaped housing 101 which is formed from two mating halves  
6 102, 104. By generally pistol-shaped, it is meant that the  
7 housing has a grip portion 108 and a barrel portion 109. Three  
8 levers (106, 118, 136) and a toothed cam (122) are rotatably  
9 mounted within the housing.

10  
11 The first lever 106 is mounted adjacent to the gripping  
12 portion 108 of the housing and is pivotally coupled at its upper  
13 end to the housing by a pin 110. A slotted throughbore 112 in the  
14 lever 106 is located below the pin 110. The slotted throughbore  
15 112 receives the proximal end of cable 26 (which controls the  
16 grasper) and the cable is attached to the lever 106 by a crosspin  
17 114. The lower end of the lever 106 is provided with a spring  
18 biased latch 116 which is operatively engageable with a notch (not  
19 shown) in the housing.

20  
21 The second lever 118 is pivotally coupled at one end 120 to  
22 the proximal end of the toothed cam 122. The second lever 118 is  
23 also provided with a slotted throughbore 124 which receives the  
24 proximal end of cable 22 (which controls the fastener firing

1 member). The proximal end of the cable 22 is coupled to the lever  
2 118 by a crosspin 126 in the slotted throughbore 124. The slotted  
3 throughbore 124 is located in a portion 118a of the lever 118  
4 which is broader than an immediately adjacent portion 118b. A  
5 locking stop 113 is provided in housing half 104 (Figure 18) which  
6 blocks movement of the broad portion 118a of the lever as  
7 described in more detail below.

8

9       The toothed cam 122 is rotatably coupled to one portion 102  
10 of the housing by a pin 128 which is located between the grip  
11 portion 108 and the barrel portion 109 of the housing. This  
12 portion of the housing is provided with a slotted wall 111 (Figure  
13 16) through which the first and second levers 106, 118 exit the  
14 housing. The slot in the wall 111 is dimensioned to allow passage  
15 of the portion 118b of the lever 118 and may be dimensioned to  
16 prevent the passage of the broader portion 118a. The cam 122 has  
17 a distal curved slotted throughbore 130 which receives the  
18 proximal end of cable 24 (which controls the rotatable fastener  
19 head). The proximal end of cable 24 is coupled to the cam 122 by  
20 a crosspin 132 which rides in the curved throughbore 130. The cam  
21 122 is provided with a plurality of peripheral teeth 134 which  
22 extend along a curved path from the proximal end of the cam where  
23 the lever 118 is coupled to it, to a point adjacent to the curved  
24 throughbore.

1       The third lever 136 is rotatably mounted above the cam 122 by  
2 a pin 138 and is provided with a plurality of radial teeth 140  
3 which engage the teeth 134 of the cam 122.

4  
5       The housing 101 is also provided with a plurality of cable  
6 guides 142 (Figure 17) in the barrel portion 109 of the housing  
7 half 102 and an endoscope receiving tube 144 (Figure 18) in the  
8 barrel portion 109 of the housing half 104. In addition, the  
9 housing halves 102, 104 are provided with longitudinal guide slots  
10 146, 148 which engage the crosspin 132 and guide its motion in a  
11 longitudinal direction.

12  
13       The operation of the actuator 100 is described in sequence  
14 with reference to Figures 16-24 and with reference to the  
15 presently preferred end effector configuration of Figures 25-31  
16 which are discussed in more detail below. Figures 16-19 show the  
17 positions of the levers 106 and 136 when the grasper is closed and  
18 the fastener head is opened (see also Figure 25). In this  
19 position of lever 136, the lever 118 is positioned so that it is  
20 impossible to move the lever 118 to fire a male fastener. In  
21 particular, the distal location of lever 136 has caused the radial  
22 teeth 140 to rotate the cam 122 proximally which has moved the  
23 pivot point 120 of the lever 118 to a position proximal of its  
24 broad portion 118a. In order to move the lever 118, the broad

1 portion 118a needs to pass the stop 113 (Figure 18) which prevents  
2 its movement. In addition, since the lever 118 must rotate about  
3 the pivot point 120, the portion 118a needs to exit the slot 111  
4 in the housing. However, as described above, the slot may be  
5 dimensioned to prevent this movement. With the levers in the  
6 positions shown in Figures 16-19, the instrument is in the proper  
7 orientation for delivery through the esophagus. It will also be  
8 appreciated that the positions and locations of the levers are  
9 easy to understand and provide intuitive indication of the  
10 positions of the parts of the end effector. For example, the  
11 lever 106 is "closed" relative to the grip 108 indicating that the  
12 grasper is closed. The lever 136 is approximately 180° forward  
13 indicating that the fastener head is rotated forward (distally)  
14 approximately 180°. The lever 118, which is most like the trigger  
15 portion of the pistol shaped actuator is raised up and out of the  
16 way where it cannot be pulled.

17

18 After the end effector is in place at the surgical site, the  
19 grasper is opened (to the position shown in Figure 26) by  
20 releasing the latch 116 and moving the lever 106 distally as shown  
21 in Figure 20; thereby moving cable 26 which is attached to the  
22 grasper 206. After the grasper has been properly positioned, the  
23 lever 106 is moved back and the latch 116 holds the grasper locked  
24 closed (in the position shown in Figure 25).

1       The rotatable fastener head is now closed (to the position  
2 shown in Figures 27-30) by rotating the lever 136 proximally which  
3 is shown in two stages in Figures 21 and 22. As seen in comparing  
4 Figures 20, 21, and 22, as the lever 136 is rotated proximally,  
5 the teeth 140 on the lever 136 engage the teeth 134 on the cam 122  
6 causing the cam 122 to rotate distally. This action causes the  
7 curved slot 130 to rotate in a manner which forces the cross pin  
8 132 to move distally in the slots 146, 148. Movement of the  
9 crosspin 132 moves the cable 24 distally causing the fastener head  
10 to close. At the same time, the pivot point 120 of the lever 118  
11 is rotated above the broad portion 118a of the lever 118. This  
12 moves the broad portion 118a above the stop 113 and places the  
13 lever 118 in a position where the broad portion 118a does not need  
14 to exit the slot 111 and can freely pass alongside the stop 113.  
15 As shown in Figure 22, the lever 118 is now operable to fire a  
16 male fastener. It will be appreciated that, until the fastening  
17 head is completely closed, movement of the firing lever 118 to  
18 pull the cable 22 is prevented by the stop 113. In addition, it  
19 will be appreciated that the crosspin coupling 126 remains  
20 stationary as the cam 122 causes the lever 118 to be rotated about  
21 this pin.

22

23       Figure 23 shows the lever 118 moved to the proximal position  
24 which pulls the cable 22 proximally and fires the male fastener

1 part (as shown in Figure 31). As seen best in Figure 24, when the  
2 firing lever is in the proximal position, the stop 113 is located  
3 below the broad portion 118a. It will be appreciated that this  
4 position of the lever 118 will prevent the lever 136 from being  
5 moved distally. Distal movement of the lever 136 will attempt to  
6 rotate the cam 122 in a manner which will move the lever 118 in a  
7 direction where its broad portion 118a must pass the stop 113.  
8 Therefore, before the lever 136 can be moved to open the fastener  
9 head, the firing lever 118 must be moved back to the position  
10 shown in Figure 22. As show in Figures 23 and 24, the lever 118  
11 is preferably concave along its proximal side so that it can be  
12 moved over the lever 106.

13

14 Turning now to Figures 25-37, the presently preferred end  
15 effector and fasteners are similar to those described above with  
16 reference to Figures 1-10 with some differences which will become  
17 apparent from the following description.

18

19 The end effector 200 has a substantially cylindrical  
20 stationary member 202, a rotatable fastener head 204, and a  
21 grasper 206. The stationary member 202 has a relatively flexible  
22 proximal portion 208 and a relatively rigid distal portion 210.  
23 The distal portion 210 has a flattened part 212 which angles down  
24 toward the distal end 214 of the stationary member 202. The

1 flattened part 212 is provided with a first grasping surface 216  
2 and the grasper 206 is provided with a second grasping surface  
3 218. A male fastener exit port 220 is located intermediate of the  
4 flattened part 212 and the proximal portion 208. As seen best in  
5 Figures 30 and 31, a firing member 222 with a movable male  
6 fastener part holder 224 is located inside the stationary member  
7 202. As seen best in Figure 29, a store 226 of male fastener  
8 parts 227 is located inside the stationary member 202, proximal of  
9 the firing member 222. Individual male fastener parts 227a are  
10 biased from the store into the male fastener part holder 224 by a  
11 spring 229 as shown in Figure 30. According to this embodiment,  
12 up to six male fastener parts are held in the store. As seen best  
13 in Figures 28 and 29, an endoscope port 228 is provided in the  
14 stationary member 222 below the male fastener part store 226.  
15 Three cable ports 230, 232, 234 are provided in the stationary  
16 member 202 as shown in Figure 29 for attaching control cables to  
17 the grasper 206, the fastener head 204, and the firing member 222,  
18 respectively.

19

20 The rotatable fastener head 204 includes a store 236 of  
21 female fastener parts 237 and a movable tray 238 for moving female  
22 fastener parts out of the store and into position to receive a  
23 male fastener part as described below. According to this  
24 embodiment, up to six female fastener parts are held in the store.

1 The movable tray 238 is coupled to the fastener head 204 by  
2 flanges 238a, 238b which slideably engage grooves 204a, 204b in  
3 the fastener head as seen best in Figures 27-30. The movable  
4 fastener head 204 is coupled to the distal end 214 of the  
5 stationary member 202 by a pivot axle 240, and a hinged link 242  
6 (Figure 28) couples the fastener head 204 to a control cable (not  
7 shown). When the link 242 is moved distally, the fastener head  
8 204 is moved to the closed position as shown in Figure 28. When  
9 in this position, the hinge 242a in the link 242 is moved past the  
10 center of the pivot axle 240 which locks the fastener head in the  
11 closed position. The sliding tray 238 is coupled via a flange  
12 238c and a pivoting link 244 to the pivot axle 240 as seen best in  
13 Figures 25 and 26. This link 244 causes the tray 238 to slide  
14 from the position shown in Figures 25 and 26 to the position shown  
15 in Figures 27 and 28 when the fastener head 204 is closed.

16  
17 The firing member 222 is coupled to the stationary member 202  
18 by the same pivot axle 240 as the fastener head as shown in  
19 Figures 25, 26, 30, 33, and 34. The firing member 222 is coupled  
20 to a control cable (not shown) by a lower flange 222a as shown in  
21 Figures 30, 33, and 34. As shown in Figure 32, the distal portion  
22 210 of the stationary member 202 is provided with a stepped port  
23 234 through which the control cable for the firing member passes  
24 and which holds the cable sheath. When the control cable pulls



1 the flange 222a proximally, the firing member 222 is moved towards  
2 the exit port 220. The movable male fastener part holder 224 is  
3 provided with a proximal flange 224a which is coupled to a lateral  
4 portion 210a of the stationary member 202 by a pivoting link 246  
5 as seen best in Figure 30. This link 246 causes the holder 224 to  
6 slide distally as shown in Figure 31 when a male fastener part is  
7 fired. The purpose of the holder 224 is to prevent the male  
8 fastener part from falling out through the port 220 when the  
9 fastener head is open and to allow the firing operation to be  
10 aborted while retaining the male fastener part.

11  
12 As seen best in Figures 33 and 34, the grasper 206 is  
13 pivotally coupled to the distal end of the firing member 222 on a  
14 pivot axle 250. The grasper 206 is also coupled to a control  
15 cable (not shown) via a hole 252 located above its pivot  
16 connection. As shown in Figures 31 and 32, the distal portion 210  
17 of the stationary member 202 is provided with a stepped port 230  
18 through which the control cable for the grasper passes and which  
19 holds the cable sheath. When the control cable is pulled  
20 proximally, the grasper is moved to the closed position shown in  
21 Figure 25.

22  
23 Turning now to Figures 35-37, the presently preferred male  
24 fastener part 227 (substantially the same as the fastener part 46

1 described above) has a disk shaped base 227a, a central upstanding  
2 shaft 227b, and tapered barb 227c at the end of the shaft. The  
3 presently preferred female fastening member 237 is a substantially  
4 flat rectangular member 237a defining a central hole 237b. The  
5 hole 237b has a tapered entry 237c and four radial strain relief  
6 slots 237d. Four flexible or frangible peripheral tabs 237e are  
7 provided on the periphery of the rectangular member. These tabs  
8 hold the fastener part in the tray 238 as shown in Figure 35, but  
9 allow it to be pulled out of the tray after it is coupled to a  
10 male fastener part as shown in Figure 37.

11

12 Turning now to Figures 38-48, an alternate preferred end  
13 effector 300 is similar to the end effector 200 described above,  
14 with similar reference numerals referring to similar parts.

15

16 The end effector 300 has a substantially cylindrical  
17 stationary member 302, a rotatable fastener head 304, and a  
18 grasper 306. The stationary member 302 has a flattened part 312  
19 which angles down toward the distal end 314 of the stationary  
20 member 302. The flattened part 312 is provided with a first  
21 grasping surface 316 and the grasper 306 is provided with a second  
22 grasping surface 318. A male fastener exit port 320 is located at  
23 the proximal end of the flattened part 312. As seen best in

1 Figures 38-44, a firing member 322 with a male fastener part  
2 holder 324 is located inside the stationary member 302.

3  
4 As seen best in Figures 41-44, the holder 324 has a pair of  
5 flanged springy arms 324a, 324b which hold the base of a male  
6 fastener part, e.g. 327a. The arms 324a, 324b are biased outward  
7 to the position shown in Figure 43. As seen best in Figures 41  
8 and 44, the interior of the stationary member 302 has contoured  
9 walls 303a, 303b which hold the arms 324a, 324b close together,  
10 securing the male fastener part. When the firing member 322 is  
11 raised into the firing position, as shown in Figures 40 and 44,  
12 the springy arms 324a, 324b move outward as shown in Figure 43,  
13 thereby releasing the male fastener part.

14  
15 As seen best in Figures 38-40, a store 326 of male fastener  
16 parts 327a, 327b, etc. is located inside the stationary member  
17 302, proximal of the firing member 322. Individual male fastener  
18 parts 327a, 327b, etc. are biased from the store into the male  
19 fastener part holder 324 by a spring (not shown). According to  
20 this embodiment, a leaf spring 325 having an upstanding flange  
21 325a and a distal tongue 325b (Figure 40) is arranged beneath the  
22 row of male fastener parts in the store 326. As shown in Figure  
23 40, the distal most fastener part is prevented from exiting the  
24 store 326 by the flange 325a when the firing member 322 is in the

1 firing position. When the firing member 322 returns from the  
2 firing position as seen in Figures 38 and 39, the tongue 325b of  
3 the leaf spring is depressed by the firing member 322 and the  
4 flange 325a is thereby moved away from the next fastener part  
5 allowing it to enter the holder 324 of the firing member 322.

6

7 As seen best in Figures 41, 44, and 48, an endoscope port 328  
8 is provided in the stationary member 322 below the male fastener  
9 part store 326. Three cable ports 330, 332, 334 are provided in  
10 the stationary member 302 as shown in Figures 41 and 44 for  
11 attaching control cables to the grasper 306, the fastener head  
12 304, and the firing member 322, respectively.

13

14 As shown in Figures 41-48, the rotatable fastener head 304  
15 includes a store 236 of female fastener parts 337 and a movable  
16 tray 338 for moving female fastener parts out of the store and  
17 into position to receive a male fastener part as described below.  
18 According to this embodiment, up to six female fastener parts are  
19 held in the store. As seen best in Figure 44, the movable tray  
20 338 is coupled to the fastener head 304 by flanges 338a, 338b  
21 which slideably engage flanges 304a, 304b in the fastener head.  
22 The sliding tray 338 is coupled via a flange 338c and a pivoting  
23 link 344 to the pivot axle 340 as seen best in Figures 44, 45, and  
24 48. This link 344 causes the tray 338 to slide from the position

1 shown in Figure 44 to the position shown in Figures 45 and 48 when  
2 the fastener head 304 is closed.

3

4 As seen best in Figures 45-48, the female fastener parts  
5 337a-337e are biased out of the store 336 by a bifurcated leaf  
6 spring 305 and are held laterally in line by a support post 307  
7 which is seen best in Figure 46 where the movable tray has been  
8 removed to better expose the spring 305 and the post 307. A  
9 fastener discharge spring 309 is located adjacent to the female  
10 fastener store 336 and is provided with a male fastener engaging  
11 surface 311. As the fastener head 304 is moved from the open  
12 position shown in Figure 46 to the closed position shown in Figure  
13 45, the movable tray 338 moves the top most female fastener part  
14 337a out of the store and over the discharge spring 309. Figure  
15 47 shows the tray 338 in a midway position as the fastener 337a is  
16 being moved into position to receive a male fastener part. When a  
17 male fastener is fired into the female fastener as shown in Figure  
18 48, The end of the male fastener will engage the surface 311 on  
19 the spring 309 and compress the spring. It will be appreciated  
20 that as the firing member 322 is returned from the firing  
21 position, the spring 309 will push against the end of the male  
22 fastener thereby pushing the female fastener out of the tray,  
23 bending or breaking the tabs of the female fastener.

24

1       The firing member 322 is coupled to the stationary member 302  
2 by the same pivot axle 340 as the fastener head as shown in  
3 Figures 39, 40, 42, 43 and 48. The firing member 322 is coupled  
4 to a control cable (not shown) by a lower flange 322a as shown in  
5 Figure 48. When the control cable pulls the flange 322a  
6 proximally, the firing member 322 is moved towards the exit port  
7 320.

8  
9       There have been described and illustrated herein several  
10 embodiments of a flexible endoscopic surgical instrument for  
11 invagination and fundoplication. While particular embodiments of  
12 the invention have been described, it is not intended that the  
13 invention be limited thereto, as it is intended that the invention  
14 be as broad in scope as the art will allow and that the  
15 specification be read likewise. It will therefore be appreciated  
16 by those skilled in the art that yet other modifications could be  
17 made to the provided invention without deviating from its spirit  
18 and scope as so claimed.